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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,650	09/29/2003	Wilhelmus Petrus Martinus Maria van Erp	CRD5049-US-NP	2353
27777	7590	05/16/2006	EXAMINER MEHTA, BHISMA	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ART UNIT 3767	PAPER NUMBER

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/673,650	Applicant(s) VAN ERP ET AL.	
	Examiner Bhisma Mehta	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/19/2003, 7/28/2004, 2/28/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "balloon in an initial configuration being deflated, pleated, and wrapped around the catheter shaft" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 46. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: on line 19 of page 4, it appears that the word "to" is missing between the words "ends" and "a". On line 4 of page 9, it is unclear what "distal portion" applicant is referring to.

Appropriate correction is required.

Claim Objections

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to describe the proximal end of the

inner tubular body and the proximal end of the outer tubular body as being affixed together. The balloon in an initial configuration being deflated, pleated and wrapped is also not described in the specification. Also, the specification fails to describe what is meant by "a single seal".

5. Claims 1-10 are objected to because of the following informalities:

a. Claim 1 recites the limitations "the proximal ends of the inner and outer tubular bodies" in line 9, "their distal ends" in line 12, and "the hypotube proximal end" in line 13. The proximal end of the inner tubular body has been established in line 5 but the proximal end of the outer tubular body has not been established. Similarly, the distal end of the inner tubular body has been established but the distal end of the outer tubular body has not been established. There is insufficient antecedent basis for these limitations in the claim. Also, the word "guidwire" in line 6 is a spelling mistake.

b. Claim 9 recites the limitation "the proximal ends of the inner and outer tubular bodies" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 2 recites the limitation "the catheter shaft" in lines 2 and 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-6, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Keith (U.S. 5,217,482). In Figure 5, Keith shows a rapid-exchange catheter comprising a stainless steel hypotube (22B), an inner tubular body (80B), and an outer tubular body (82B). The hypotube has a proximal tubular portion, an intermediate tubular portion (117) having a longitudinal indentation (72B), and a distal portion (74B). The proximal portion of the hypotube is cylindrical. The distal portion of the hypotube extends into the outer tubular body. In lines 37-65 of column 8, Keith teaches that it is desirable to provide a transition in flexibility between the tubular portions of the hypotube to the inner and outer tubular bodies. The inner tubular body has a proximal guidewire port, a distal guidewire port, and a guidewire lumen (52) which extends between the ports. In lines 37-62 of column 7, Keith teaches sealing the proximal end of the outer tubular portion

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(82) to the hypotube (66) with a single seal and sealing the proximal end of the inner tubular portion (80) to the hypotube (66) with a single seal adjacent the bonding region (74) as shown in Figure 2. Figure 2 also shows an inflation lumen (62 and 104) which extends through the proximal and intermediate tubular portions of the hypotube and through the annular space between the inner and outer tubular bodies into the interior of a balloon ((26). The proximal collar (36) and the distal collar (40) of the balloon are affixed to the inner and outer tubular bodies. With regards to claim 2, since Keith teaches inflating and deflating the balloon, a deflated configuration of the balloon would be in folds and wrapped around the outer tubular body. In lines 26-30 of column 10, Keith teaches the hypotube as being a single tubular shaft. With regards to claims 4 and 5, the distal portion of the hypotube has an arcuate cross-section (72B) and the longitudinal portion of the hypotube is shallower in the proximal direction and deeper in the distal direction as shown at 68B in Figure 5.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith in view of Ressemann et al (U.S. 5,425,711).

Keith discloses a rapid-exchange balloon catheter as claimed. Even though Keith teaches that it is desirable to provide a transition in flexibility between the tubular portions of the hypotube to the inner and outer tubular bodies, Keith does not teach a tapering portion between the proximal cylindrical portion and the indented intermediate portion. In Figure 5, Ressemann et al show a rapid-exchange balloon catheter with a stainless steel hypotube (23) having a tapering portion between an proximal cylindrical portion (32) and an indented intermediate portion (68) and teach that it is desirable for a catheter to have a relatively stiff proximal portion and a relatively flexible distal portion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter of Keith to include a tapering portion between the proximal cylindrical portion and the indented intermediate portion as taught by Ressemann et al to provide more flexibility to the catheter thus allowing it to be more easily guided to a desired body location.

Even though Keith teaches using a balloon catheter in angioplasty procedures, Keith does not specifically teach the catheter having a stent crimped around the balloon. In lines 19-26 of column 4, Ressemann et al teach that it is well known that the components of the rapid-exchange balloon catheter as disclosed could also be used on other catheters such as stent delivery catheters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a stent on the balloon catheter of Keith as both Keith and Ressemann et al disclose using balloon catheters for angioplasty procedures and Ressemann et al teach that stent delivery catheters are well known in the art of angioplasty procedures.

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Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Euteneuer et al (U.S. 4,943,278), Yock (U.S. 5,300,085), Blaeser et al (U.S. 5,490,837), Enger (U.S. 5,980,486), Stivland et al (U.S. 6,548,010) and Happ et al (U.S. 6,575,958) disclose balloon catheters which are used in angioplasty procedures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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KEVIN SIRMONS
PRIMARY EXAMINER

Kevin C. Sirmons